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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,025	08/26/2003	Nicholas G. Bacopoulos	24852-501 CIP3	6445

35437 7590 07/06/2005

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NEW YORK, NY 10017

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,025

Applicant(s)

BACOPOULOS ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-40 and 46-67 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-40 and 46-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-13-05</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants Amendment filed April 11, 2005 is acknowledged. New claims 62-67 are presented. Accordingly, claims 1, 2, 8-40 and 46-67 are now under consideration wherein suberoylanilide hydroxamic acid (SAHA) remains the elected species.

Three Information Disclosure Statements filed April 11, 2005, May 5, 2005 and May 13, 2005 are further acknowledged and have been reviewed.

In the last Office Action the Amendment filed December 22, 2003 was objected to under 35 U.S.C. 132 because it introduced new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

In response to each instance cited in the last Office Action, Applicants have either canceled the subject matter in question or pointed to those sections of the specification where support is provided.

There remains one issue. On page 29, the recitation "and/or the anti-cancer agents" is new matter with respect to the recitation "or".

The objection is maintained.

Claims 1, 2, 8-40 and 46-61 were rejected in the last Office Action under 35 U.S.C. 103(a) as being unpatentable over Jackson et al., US2003/0161830. It was asserted Jackson teaches the administration of modulators of human histone deacetylases for use in the treatment of cancers. Jackson additionally teaches the specific inhibitory effect on histone deacetylase activity exhibited by the compound suberoylanilide hydroxamic acid (SAHA). See page 1, paragraph [0008], and page 17, paragraph [0165]. Included among the types of cancers contemplated by Jackson that

Art Unit: 1614

are treatable by administration of a HDAC modulator is mesothelioma. See page 21, paragraph [0209].

Applicants argue Jackson provides a list of HDAC inhibitors, most of which are not hydroxamic acids, and a list of diseases for treatment of which mesothelioma is recited. Applicants urge Jackson presents no instructions regarding which HDAC inhibitors to use for which types of diseases.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record is repeated for the reasons of record and presently extended to new claims 62-67. Histone deacetylase inhibitors, such as SAHA, are well established in the prior art as effective in a variety of different types of neoplastic diseases including leukemic cell lines, as well as solid tumors. See, for example, Adams et al., Oncogene, page 6688, which is cited only to show the state of the art. Jackson specifically includes mesothelioma among those cancers that are responsive to a therapeutic regimen comprising administering a modulator of histone deacetylase.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any

Art Unit: 1614

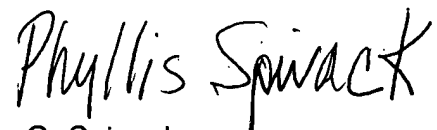
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 517-272--0951. The fax phone number for the organization where this application or proceeding is assigned is 571-873-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis G. Spivack
Primary Examiner
Art Unit 1614



PHYLLIS SPIVACK
PRIMARY EXAMINER

July 2, 2005